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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,467	01/22/2002	Garry P. Nolan	A-64259-2/RMS/AMS	9737

24353 7590 11/15/2004

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EXAMINER	
BRUSCA, JOHN S	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 11/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/057,467	NOLAN, GARRY P.	
	Examiner	Art Unit	
	John S. Brusca	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 May 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 16 July 2004 and 23 September 2004 have been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 8-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In In re Wands (8 USPQ2d 1400 (CAFC 1988)) the CAFC considered the issue of enablement in molecular biology. The CAFC summarized eight factors to be considered in a determination of "undue experimentation." These factors include: (a) the quantity of experimentation necessary; (b) the amount of direction or guidance presented; (c) the presence or absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the relative skill of those in the art; (g) the predictability of the art; and (h) the breadth of the claims.

In considering the factors for the instant claims:

a) In order to practice the claimed invention one of skill in the art must use a method of assay of a random peptide that alters a phenotype of a cell by interaction with a cellular protein that is not produced using a nucleic acid made using recombinant DNA technology. For the reasons discussed below there would be an unpredictable amount of experimentation required to use the claimed method.

b) The specification presents guidance to assay for a peptide that alters a phenotype of a cell. The specification discusses cis and trans dominant effects of a protein on pages 6-7. The specification states that a transdominant effect affects the activity of a second target while a cis effect affects the activity of a first target, however the specification does not show how the effects can be distinguished at the phenotype level. The specification does not provide guidance to use an assay of a random peptide that alters a phenotype of a cell by interaction with a cellular protein that is not produced using a nucleic acid made using recombinant DNA technology because there is no guidance to determine interaction between a random peptide and a cellular protein that is not produced using a nucleic acid made using recombinant DNA technology.

c) The specification shows a working example of an assay for a peptide that alters a phenotype of a cell on page 13 in which an IL-3 dependent cell line is transfected with a retroviral library that expresses random peptides. Clones were selected for growth in the absence of IL-3. The specification states that random peptides selected in the clones might facilitate growth by either positive or negative effects. The specification does not contain a working example of determining interaction between a random peptide and a cellular protein that is not produced using a nucleic acid made using recombinant DNA technology. The working example

shows detection of a phenotype (growth) produced by the random peptide. The working example does not show detection of an interaction between a random peptide and a cellular protein.

d) The nature of the invention, protein binding assays, is complex.

e) Yang et al. shows in the abstract and throughout a yeast two-hybrid assay in which a random peptide that alters a phenotype of a cell by interaction with a cellular protein that is produced using a nucleic acid made using recombinant DNA technology. The library of random peptides are fused to a Gal4 domain (see figure 1). Binding of the random peptide to a retinoblastoma domain-Gal4 fusion protein results in an altered phenotype of the host cell due to expression of reporter genes HIS3 to produce a his^+ phenotype. In the conclusion on page 1155, Yang et al. state that their method can be used to identify peptides with a desired binding affinity, to identify peptides that inhibit protein-protein interactions, and to study the phenotypic consequences of such interactions in living cells. Yang et al. does not show an assay of a random peptide that alters a phenotype of a cell by interaction with a cellular protein that is **not** produced using a nucleic acid made using recombinant DNA technology.

f) The skill of those in the art of protein interactions is high.

g) The prior art does not predict or discuss an assay of a random peptide that alters a phenotype of a cell by interaction with a cellular protein that is not produced using a nucleic acid made using recombinant DNA technology. The prior art does not show detection of such interactions.

h) The claims are broad in that they are drawn to an assay of a random peptide that alters a phenotype of a cell by interaction with a cellular protein that is not produced using a nucleic acid made using recombinant DNA technology. The claims require detection of interactions with

cellular proteins without the limitation that the cellular protein is modified by recombinant DNA technology so that interaction is detectable.

The skilled practitioner would first turn to the instant specification for guidance in practicing the claimed method. However, the specification does not show how to detect interactions between random peptides and cellular proteins. As such the skilled practitioner would turn to the prior art for such guidance, however the prior art does not show such guidance. Finally, said practitioner would turn to trial and error experimentation to practice the claimed method. Such represents undue experimentation.

Claim Rejections - 35 USC § 103

4. The rejection of claims 8-20 under 35 U.S.C. 103(a) as being unpatentable over Yang et al. in view of Fearon et al. in view of Rayner et al. in view of Gonda et al. in the Office action mailed 18 May 2004 is withdrawn in view of the amendment to claim 8 filed 23 September 2004.

5. The rejection of claims 21-23 under 35 U.S.C. 103(a) as being unpatentable over Yang et al. in view of Fearon et al. in view of Rayner et al. in view of Kauffman et al. in the Office action mailed 18 May 2004 is withdrawn in view of the amendment to claims 21-23 filed 23 September 2004..

6. The rejection of claims 24 and 25 under 35 U.S.C. 103(a) as being unpatentable over Yang et al. in view of Fearon et al. in view of Rayner et al. in view of Kauffman et al. as applied to claims 21-23 above, and further in view of Abbas et al. in the Office action mailed 18 May 2004 is withdrawn in view of the amendment to claim 23 filed 23 September 2004.

Terminal Disclaimer

7. The terminal disclaimers filed on 16 July 2004 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. copending applications 08/589911, 09/916940, 09/918601, 09/919635, and U.S. Patent No. 6,153,380 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Double Patenting

8. The rejection of claims 8, 9, 11-17, 19, and 20-25 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 5-15, 19-21, and 27 of U.S. Patent No. 6,153,380 is withdrawn in view of the terminal disclaimer filed 16 July 2004.

The provisional rejection of claims 8, 11-17,. and 19 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 26, 27, 29, and 31-37 of copending Application No. 09/919635 is withdrawn in view of the terminal disclaimer filed 16 July 2004.

The provisional rejection of claims 8-11, 14-17, and 20 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 23-26, 28-30, 34-37, 43, and 44 of copending Application No. 09/918601 is withdrawn in view of the terminal disclaimer filed 16 July 2004.

The provisional rejection of claims 9-12, and 14-17 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 23-25, 28, 30-33, 34, and 39 of copending Application No. 09/916940 is withdrawn in view of the terminal disclaimer filed 16 July 2004.

The provisional rejection of claims 8, 11, and 19 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of copending Application No. 08/589911 is withdrawn in view of the terminal disclaimer filed 16 July 2004.

Conclusion

9. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center at (800) 786-9199.Any inquiry concerning this communication or earlier communications from the examiner should be directed to John S. Brusca whose telephone number is 571 272-0714. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on 571 272-0722. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

J.S. Brusca 10 November 2004

John S. Brusca
Primary Examiner
Art Unit 1631

jsb